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Washington, D.C. 20231

Sir:

Transmitted herewith for filing is the reissue patent application of U.S. Patent 5,732,711 by:

MAR 3 0 2000

INVENTOR: Citizenship:

Post Office Address/

Residence:

INVENTOR:

US 694 Spruce Road

Warminster, Pennsylvania 18974

Joseph F. Fitzpatrick

Anthony C. Romano

Citizenship: Post Office Address/

Residence: INVENTOR:

John H. Richards

110 Canterbury Lane

US

US

Cıtızenship: Post Office Address/ 2032 Grey Horse Drive

Residence: INVENTOR: Warrington, Pennsylvania 18976

1301 Morgan Avenue

Lansdale, Pennsylvania 19446

Ronald S. Kolarovic US

Citizenship: Post Office Address/

Residence:

Cinnaminson, New Jersey 08077 Hill-Rom Air-Shields, Inc.

For:

BODY FUNCTION MEASURING APPARATUS

Enclosed are:

Assignee:

The Specification, including claims and abstract (13 pages);

3 sheets of 3 formal drawing(s);

Executed Statement under 37 CFR 3.73(b);

Executed Offer to Surrender Original Patent under 37 CFR 1.178;

Unexecuted Declaration by Inventors;

Request for Title Report.

The filing fee has been calculated as shown below:

For	No. Filed		No. Extra	Small/Large Entity	Total
Basic Fee:				+\$345/690=	\$690.00
Total Claims:	34	- 20 =	14	x \$9/18 =	\$252.00
Independent Claims:	6	- 3=	3	x \$39/78 =	\$234.00
Multiple Dep. Claim Presented:	0			+\$130/260	\$ 0.00
TOTAL FEES:					\$1,176.00

A check for the filing fee in the amount of \$1,176.00 is enclosed. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 02-1010 (7175/60314).

> Mark M. Newman Reg. No. 31,472

Barnes & Thornburg Franklin Tower Bldg. 1401 Eye Street, N.W. Suite 500 Washington, D.C. 20005 (202) 289-1313

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

SPECIFICATION

INVENTION: BODY FUNCTION MEASURING APPARATUS

INVENTOR: Joseph F. Fitzpatrick

Citizenship: US

Post Office Address/ 694 Spruce Road

Residence: Warminster, Pennsylvania 18974

INVENTOR: Anthony C. Romano

Citizenship: US

Post Office Address/ 110 Canterbury Lane

Residence: Lansdale, Pennsylvania 19446

INVENTOR: John H. Richards

Citizenship: US

Post Office Address/ 2032 Grey Horse Drive

Residence: Warrington, Pennsylvania 18976

INVENTOR: Ronald S. Kolarovic

Citizenship: US

Post Office Address/ 1301 Morgan Avenue

Residence: Cinnaminson, New Jersey 08077

ATTORNEYS: BARNES & THORNBURG

1313 Merchants Bank Building

11 S. Meridian Street

Indianapolis, Indiana 46204

(317) 236-1313

BODY FUNCTION MEASURING APPARATUS

TECHNICAL FIELD

The present invention relates, in general, to the measurement of body functions with sensors in contact with the skin of a human being and, in particular, to a unit which, in addition to measuring a body function, provides an indication when the sensor in contact with the skin becomes dislodged from the skin. Although the present invention will be described in connection with skin temperature measurement, it will be apparent that the present invention has broader application.

BACKGROUND OF THE INVENTION

Many probes are in use today to measure or monitor a function of the body with which the probe is in contact or to control or influence a body state or condition. For example, a signal representative of the skin temperature of an infant in an incubator can be used to display the of the infant and can be used to control the incubator heater to regulate the thermal environment of the incubator. In such an application, it is important that intimate contact between the skin and the probe contact surface which carries the temperature sensor be established and maintained. Should the probe become dislodged, resulting in a total or partial loss of contact, the temperature indication will be incorrect and the control of the incubator heater will be other than what is desired, quite possibly leading to dangerous consequences.

Many loose probe indicators have been suggested or put into actual use. Some are based on using the signals representative of the body function being measured to detect a loose probe condition. Others are based on directly measuring some characteristic of the contact, such as impedance, which changes as the contact changes. Yet others incorporate in the probe special sensors, for example optical sensors, which detect changes in the position of the probe relative to the skim Generally, the operation and reliability of the prior art loose probe indicators have not been sufficiently satisfactory.

temperature

SUMMARY OF THE INVENTION

Body function measuring apparatus, constructed in accordance with the present invention, includes a housing and first and second identical sensors spaced apart in the housing and adapted for contact with generally the same area of skin for developing first and second body function signals, respectively. This skin temperature measuring apparatus also includes means responsive to the first body function signal and the second body function signal for developing an indication of the body function at the skin with which the first sensor and the second sensor are in contact and detecting a difference between the rate of change of the first body function signal and the rate of change of the second body function signal which exceeds a predetermined threshold representing a difference in the proximity of the first sensor to the skin and the proximity of the second sensor to the skin.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a bottom view of the sensor portion of body function measuring apparatus constructed in accordance with the present invention.

FIG. 2 is a functional block diagram of the signal processing portion of body function measuring apparatus constructed in accordance with the present invention.

FIG. 3 is a circuit block diagram of the signal processing portion of body function measuring apparatus constructed in accordance with the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring to FIG. 1, body function measuring apparatus, constructed in accordance with the present invention, includes a housing 10 and first and second identical sensors 12 and 14 spaced apart in the housing and adapted for contact with generally the same area of skin for developing first and second body function signals, respectively. When the body function measuring apparatus of the present invention is adapted for measuring body temperature, first and second identical sensors 12 and 14 are identical thermistors. The first and second signals developed by sensors 12 and 14, respectively, are conducted by wires 15 and 16 to a connector 17 which is adapted for connection to a unit for displaying a reading of the body function being measured or to control apparatus for controlling the environment of an incubator or both. From this point on, the present invention will be described as applied for skin temperature measurements, although, as indicated above, the present invention has broader application.

Preferably, first thermistor 12 and second thermistor 14 are mounted on a flexible substrate 18 which has first and second lands 18a and 18b on which first thermistor 12 and second thermistor 14, respectively, are mounted. A neck | 16e | 18c extends between first land 18a and second land 18b and has a width narrower than the width of the first land and the second land.

The flexibility of substrate 18 and its configuration, namely the arrangement of neck 18c extending between first land 18a and second land 18b, enhances the freedom of movement away from the skin of one or the other of thermistors 12 and 14 when the particular thermistor is in partial, rather than full, contact with the skin. A condition of partial contact with the skin of either of the thermistors is likely to lead to incorrect temperature indications. By improving the chances of a partially loose thermistor to move further away from the skin, the relative proximities of the thermistors to the skin will lead to a quicker and more accurate indication of a loose probe condition.

Skin temperature measuring apparatus, constructed in accordance with the present invention, also includes means responsive to the first temperature signal developed by thermistor 12 and the second temperature signal developed by thermistor 14 for developing an indication of the temperature of the skin with which the first thermistor and the second thermistor are in contact and detecting a difference between the rate of change of the first temperature signal and the rate of change of the second temperature signal which exceeds a predetermined threshold representing a difference in the proximity of first thermistor 12 to the skin and the proximity of second thermistor 14 to the skin. Referring to FIG. 2, which is a functional block diagram of the signal processing portion of skin temperature measuring apparatus constructed in accordance with the present invention, the first temperature signal T1 is representative of the temperature of the skin with which the first thermistor 12 and the second thermistor 14 are in contact and is provided as one output.

Second temperature signal T2 is inverted by an inverter 20. The first temperature signal T, and the inverted second temperature signal T2 are differentiated by differentiating circuits 22 and 24, respectively, to develop signals representative of the rate of change of the first temperature signal and the rate of change of the second temperature signal, respectively. The differentiated first temperature signal and the differentiated second temperature signal are combined in

a summing circuit 26 to develop, as a second output, a signal representative of the difference between the rate of change of the first temperature signal and the rate of change of the second temperature signal which, if exceeding a predetermined threshold, represents a difference in the proximity of first thermistor 12 to the skin and the proximity of second thermistor 14 to the skin.

Skin temperature measuring apparatus, constructed in accordance with the present invention, preferably also includes means responsive to first temperature signal T_1 and second temperature signal T_2 for detecting a difference between the first temperature signal and the second temperature signal which exceeds a predetermined threshold representing a failure of one of first thermistor 12 and second thermistor 14. As shown in FiG. 2, the inverted second temperature signal T_2 is combined with the first temperature signal T_1 in a summing circuit 28 to develop, as a third output, a signal representative of the difference between first temperature signal T_1 and second temperature signal T_2 .

The functions described in connection with FIG. 2 can be implemented by either hardware of software, each of which are represented by the circuit block diagram of FIG. 3. First temperature signal T₁, developed by first thermistor 12, is supplied to a temperature indicator/controller 30 which provides a visual indication of the temperature of the skin with which thermistor 12 is in contact and also serves as a control of the temperature of the space within an incubator hood.

First temperature signal T1 and second temperature signal T2, developed by second thermistor 14, are supplied to a differential circuit 32 which develops a signal representative of the difference, if any, between first temperature signal T and second temperature signal T2. If there is a and this difference exceeds a first predetermined threshold "A", for example ten degrees, indicative of a failure of either first thermistor 12 or second thermistor 14, an output is developed on a line "Y" and an indication of this difference or failure is provided by a failure indicator 34. If there is a difference between first temperature signal [T] and second temperature T2 and this difference is less than the first predetermined threshold "A" but greater than a second predetermined threshold "B", an output is developed on a line "N" and the combination of a level sensing circuit 36 and a differentiating circuit 38 develop a signal representative of the difference between the rate of change of the first temperature signal T_1 and the rate of change of the second temperature signal T2 which, if exceeding a predetermined third threshold "C", represents a difference in the proximity of first thermistor 12 to the skin and the proximity of second thermistor 14 to the skin, namely a loose probe condition. The loose probe condition is indicated by a loose probe indicator 40.

difference between first temperature signal T₁ and second temperature signal T₂

 $\mathbf{I}_{\mathbf{i}}$

signal **4**

It should be noted that, although a loose probe condition produces a difference between in the first temperature signal T_1 and the second temperature signal T_2 , determining the difference between the rate of change of the first temperature signal T₁ and the rate of change of the second temperature signal T2 provides a more reliable indication of a loose probe condition. Certain effects, such as thermistors and other sensors wearing over time, produce a difference between the first temperature signal T_1 and the second temperature signal T₂, so that a difference between the first temperature signal T₁ and the second temperature signal T₂ is not necessarily due to partial or complete probe dislodgement. Such effects, however, would not produce an appreciable, if any, difference between the rate of change of the first temperature signal T₁ and the rate of change of the second temperature signal T2. In contrast, the difference between the first temperature signal T₁ and the second temperature signal T₂, with a threshold for this difference set sufficiently high, is useful for identifying a failure of of the thermistors which would cause a significant difference between the first temperature signal T_1 and the second temperature signal T_2 -

While there have been described preferred embodiments of the present invention, it should be obvious to those skilled in the art that various modifications and changes can be made without departing from the true spirit and scope of the invention.

What is claimed:

1. Skin temperature measuring apparatus comprising: a housing;

first and second [identical thermistors] <u>temperature sensors</u> spaced apart in said housing but in proximity to each other and adapted for contact with generally the same area of skin for developing first and second temperature signals, respectively; and

means responsive to said first temperature signal and said second temperature signal for:

- (a) developing an indication of the temperature at the skin with which said first [thermistor] and said second temperature sensors [thermistor] are in contact. and
- (b) detecting a difference between the rate of change of said first temperature signal and the rate of change of said second temperature signal which exceeds a predetermined threshold representing a difference in the proximity of said first [thermistor] temperature sensor to the skin and the proximity of said second [thermistor] temperature sensor to the skin.
- 2. Skin temperature measuring apparatus according to claim 1 further including means responsive to said first temperature signal and second temperature signal for detecting a difference between said first temperature signal and said second temperature signal which exceeds a predetermined threshold representing a failure of one of said first [thermistor] and said second [thermistor] temperature sensors.
- 3. Skin temperature measuring apparatus according to claim 1 further including a flexible substrate on which said first [thermistor] and said second [thermistor] temperature sensors are mounted.
- 4. Skin temperature measuring apparatus according to claim 3 wherein said substrate has:
 - (a) first and second lands on which said first [thermistor] and said second [thermistor] temperature sensors, respectively, are mounted, and
 - (b) a neck extending between said first land and said second land and having a width narrower than the width of said first land and said second land.

5. Body function measuring apparatus comprising: a housing;

first and second [identical] sensors spaced apart in said housing but in proximity to each other and adapted for contact with generally the same area of skin for developing first and second body function signals, respectively; and

means responsive to said first body function signal and said second body function signal for:

- (a) developing an indication of the body function at the skin with which said first sensor and said second sensor are in contact, and
- (b) detecting a difference between the rate of change of said first body function signal and the rate of change of said second body function signal which exceeds a predetermined threshold representing a difference in the proximity of said first sensor to the skin and the proximity of said second sensor to the skin.
- 6. Body function measuring apparatus according to claim 5 further including means responsive to said first body function signal and said second body function signal for detecting a difference between said first body function signal and said second body function signal which exceeds a predetermined threshold representing a failure of one of said first sensor and said second sensor.
- 7. Body function measuring apparatus according to claim 5 further including a flexible substrate on which said first sensor and said second sensor are mounted.
- 8. Body function measuring apparatus according to claim 7 wherein said substrate has:
 - (a) first and second lands on which said first sensor and said second sensor, respectively, are mounted, and
 - (b) a neck extending between said first land and said second land and having a width narrower than the width of said first land and said second land.

9. <u>A skin temperature measuring apparatus comprising:</u> a housing;

at least a first and second temperature sensor spaced apart is said housing, but in proximity to each other and adapted for contact with generally the same area of skin for developing first and second temperature signals, respectively;

a first indicator connected to one of said at least first and second temperature sensors to indicate the temperature of the skin, and

a second indicator connected to at least both of said at least first and second temperature sensors to produce an output indicating an improper sensing of the skin temperature at that same area by at least one of the at least first and second temperature sensors.

- 10. The skin temperature apparatus of claim 9, wherein the housing is provided with a flexible substrate on which the at least first and second temperature sensors are mounted.
- 11. The skin temperature measuring apparatus of claim 9, wherein the second indicator produces an output when the temperatures sensed by the at least first and second temperature sensors differ by a threshold amount.
- 12. The skin temperature apparatus of claim 11, wherein the housing is provided with a flexible substrate on which the at least first and second temperature sensors are mounted.
- 13. The skin temperature measuring apparatus of claim 11 having a third indicator connected to said at least first and second temperature sensors which produces an output indicating an improper sensing of the skin temperature when the rate of change of the temperature sensors differ by a second threshold amount.
- 14. The skin temperature apparatus of claim 13, wherein the housing is provided with a flexible substrate on which the at least first and second temperature sensors are mounted.

- 15. The skin temperature measuring apparatus of claim 9, wherein the second indicator produces an output when the rate of change of temperatures sensed by the at least first and second temperature sensors differ by a threshold amount.
- 16. The skin temperature apparatus of claim 14, wherein the housing is provided with a flexible substrate on which the at least first and second temperature sensors are mounted.
 - 17. <u>A method of producing a skin temperature comprising:</u>

placing a housing mounted with at least two spaced apart temperature sensors adjacent the same area of skin;

providing a first indicator connected to and displaying the temperature of at least one of the at least two sensors; and

providing a second indicator connected to both the at least first and second temperature sensor and producing an indication that the displayed temperature from the first indicator is in error.

- 18. The method of claim 17, wherein the second indicator indicates that one of the at least first and second temperature sensors is malfunctioning.
- 19. The method of claim 18, wherein a third indicator is provided that is connected to both the at least first and second temperature sensors and producing an indication that the at least first and second temperature sensors are not measuring the temperature of the skin at the same area.
- 20. The method of claim 17, wherein the second indicator indicates that the at least first and second temperature sensors are not measuring the temperature at the same skin area.
 - 21. <u>A body function measuring apparatus comprising</u>

a first sensor positioned to detect the body function and to provide a first signal in response to the body function,

a second sensor positioned to detect the body function and to provide a second signal in response to the body function,

an indicator, and

a circuit operatively coupled to the indicator, the first sensor, and the second sensor, the circuit being configured to activate the indicator in response to the rate of change of the first signal and the rate of change of the second signal.

- 22. The body function measuring apparatus of claim 21, wherein the circuit detects a difference between the rate of change of the first temperature signal and the rate of change of the second temperature signal.
- 23. The body function measuring apparatus of claim 22, wherein the circuit activates the indicator when the difference between the rate of change of the first temperature signal and the rate of change of the second temperature signal exceed a predetermined threshold.
- 24. The body function measuring apparatus of claim 21, further comprising a second indicator operatively coupled to the circuit.
- 25. The body function measuring apparatus of claim 24, wherein the circuit is configured to activate the second indicator when the difference between the first signal and the second signal exceeds a predetermined threshold.

- 26. The body function measuring apparatus of claim 24, wherein the second indicator is configured to display the status of the body function.
- 27. The body function measuring apparatus of claim 26, further comprising a third indicator operatively coupled to the circuit.
- 28. The body function measuring apparatus of claim 27, wherein the circuit is configured to activate the third indicator when the difference between the first signal and the second signal exceeds a predetermined threshold.
 - A body function measuring apparatus comprising
 a first sensor providing a first signal,
 a second sensor spaced apart from the first sensor, the second sensor being positioned

a circuit coupled to the first and second sensors, the circuit comparing the rate of change of the first signal to the rate of change of the second signal, and

to lie proximate the first sensor, the second sensor providing a second signal,

an indicator operatively coupled to the circuit to indicate whether the difference between the rate of change of the first signal and the rate of change of he second signal exceeds a threshold.

30. The body function measuring apparatus of claim 29, further comprising a housing, the first sensor being received by the housing and the second sensor being received by the housing.

- 31. The body function measuring apparatus of claim 30, wherein the housing is formed to include a first land and a second land, the first sensor being carried by the first land and the second sensor being carried by the second land.
 - 32. The body function measuring apparatus of claim 31, wherein the housing is flexible.
- 33. The body function measuring apparatus of claim 31, wherein the housing is formed to include a neck connecting the first land to the second land.
- 34. The body function measuring apparatus of claim 33, wherein the neck is flexible so that the first land can move relative to the second land.

ABSTRACT

Body function measuring apparatus which provides: (1) an indication of the body function being measured, and (2) a loose probe condition by determining that the difference between the rate of change of a first body function signal, developed by a first sensor in the probe, and the rate of change of a second body function signal, developed by a second sensor in the probe, exceeds a predetermined threshold.

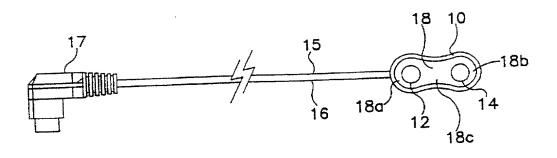
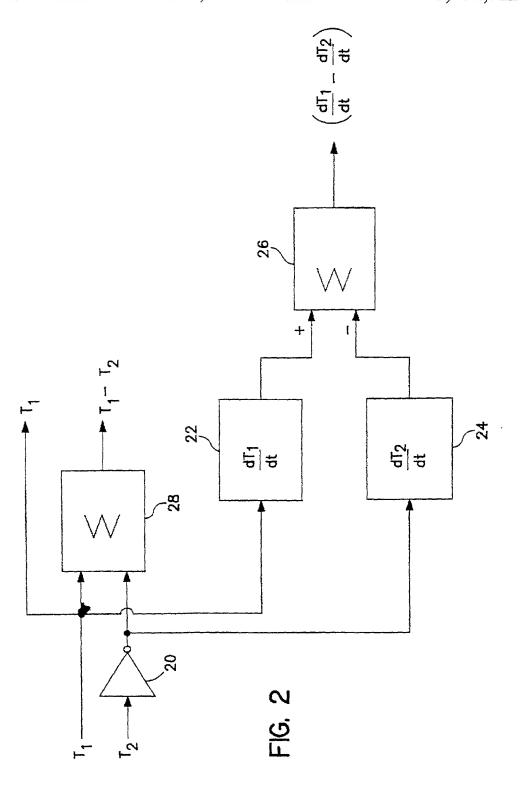


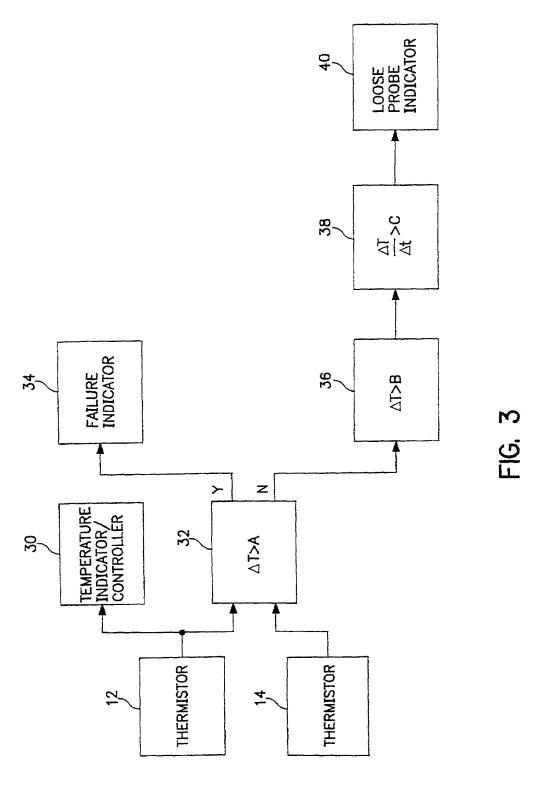
FIG. I





Mar. 31, 1998







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Fitzpatrick et al.

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Reissue of U.S. Patent No. 5,732,711

Issued March 31, 1998

on U.S. Application Serial No. 703,794

Filed August 27, 1996

DECLARATION BY INVENTORS

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

We, Joseph F. Fitzpatrick, Anthony C. Romano, John H. Richards, and Ronald S. Kolarovic declare that we are citizens of the United States of America; that we verily believe ourselves to be the original and first inventors of the invention described and claimed in U.S. Letters Patent No. 5,732,711 (hereinafter '711 PATENT) and in the foregoing specification and for which invention we solicit a reissue patent; that we do not know and do not believe that said invention was ever known or used in the United States of America before our invention thereof; and that we verily believe the '711 PATENT to be wholly or partly inoperative or invalid by reason of our claiming less than we had a right to claim in the '711 PATENT.

We request that we be permitted to amend the '711 PATENT and be granted a reissue patent; that errors rendering the '711 PATENT wholly or partly inoperative or invalid caused the claims of such patent to be of more narrow scope than necessary to distinguish over the prior art; and that such errors arose without any deceptive intent.

Specifically, we at least claimed less than we had a right to claim in the '711 PATENT by included in said patent claim 1 a specific type of temperature sensor.

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We have reviewed and understand the contents of the specification as amended herein, including amended original patent claims 1-8, as well as new claims 9-34.

We acknowledge our duty to disclose information of which we are aware which is material to patentability as defined in Title 37, Code of Federal Regulations §1.56; and we

further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the application for reissue or any patent issuing thereon.

We hereby appoint William R. Coffey, Reg. No. 24023; Jerry E. Hyland, Reg. No. 20904; Richard D. Conard, Reg. No. 27321; Steven R. Lammert, Reg. No. 27653; Richard A. Rezek, Reg. No. 30796; Timothy E. Niednagel, Reg. No. 33266; John P. Breen, Reg. No. 38833; Jill L. Woodburn, Reg. No. 39874; Nancy J. Harrison, Reg. No. 27083; R. Trevor Carter, Reg. No. 40549; Dilip A. Kulkarni, Reg. No. 27510; Perry Palan, Reg. No. 26213; Mark M. Newman, Reg. No. 31472; Bobby B. Gillenwater, Reg. No. 31105; Paul B. Hunt, Reg. No. 37154; Michael S. Gzybowski, Reg. No. 32816; and Robert D. Null, Reg. No. 40746, our attorneys, with full power of substitution and revocation, to prosecute this application, and to transact all business in the Patent and Trademark Office connected therewith; and we specify that communications regarding this application to reissue be directed to:

Richard D. Conard
BARNES & THORNBURG
1313 Merchants Bank Building
11 S. Meridian Street
Indianapolis, Indiana 46204

10/1/00 Date /

Voseph/F. Fitzpatrick

894 Spruce Road

Warminster, Pennsylvania 18974

Date

Anthony C. Romano 110 Canterbury Lane

Lansdale, Pennsylvania 19446

Date	John H. Richards 2032 Grey Horse Drive Warrington, Pennsylvania 18976
Date	Ronald S. Kolarovic 1301 Morgan Avenue Cinnaminson, New Jersey 08077

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Date

Warminster, Pennsylvania 18974

Joseph F. Fitzpatrick

694 Spruce Road

10 17 00 Date 1

Anthony C. Romano 110 Canterbury Lane

Lansdale, Pennsylvania 19446

Date	John H. Richards 2032 Grey Horse Drive Warrington, Pennsylvania 18976
	•
Date	Ronald S. Kolarovic
	1301 Morgan Avenue
	Cinnaminson, New Jersey 08077

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We acknowledge our duty to disclose information of which we are aware which is material to patentability as defined in Title 37, Code of Federal Regulations §1.56; and we

further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the application for reissue or any patent issuing thereon.

We hereby appoint William R. Coffey, Reg. No. 24023; Jerry E. Hyland, Reg. No. 20904; Richard D. Conard, Reg. No. 27321; Steven R. Lammert, Reg. No. 27653; Richard A. Rezek, Reg. No. 30796; Timothy E. Niednagel, Reg. No. 33266; John P. Breen, Reg. No. 38833; Jill L. Woodburn, Reg. No. 39874; Nancy J. Harrison, Reg. No. 27083; R. Trevor Carter, Reg. No. 40549; Dilip A. Kulkarni, Reg. No. 27510; Perry Palan, Reg. No. 26213; Mark M. Newman, Reg. No. 31472; Bobby B. Gillenwater, Reg. No. 31105; Paul B. Hunt, Reg. No. 37154; Michael S. Gzybowski, Reg. No. 32816; and Robert D. Null, Reg. No. 40746, our attorneys, with full power of substitution and revocation, to prosecute this application, and to transact all business in the Patent and Trademark Office connected therewith; and we specify that communications regarding this application to reissue be directed to:

Richard D. Conard
BARNES & THORNBURG
1313 Merchants Bank Building
11 S. Meridian Street
Indianapolis, Indiana 46204

.

Date	Joseph F. Fitzpatrick 694 Spruce Road Warminster, Pennsylvania 18974	
Date	Anthony C. Romano 110 Canterbury Lane Lansdale, Pennsylvania 19446	

John H. Richards

2032 Grey Horse Drive Warrington, Pennsylvania 18976

Date

Ronald S. Kolarovic

1301 Morgan Avenue Cinnaminson, New Jersey 08077

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Fitzpatrick et al.

Serial No.:

unknown

Art Unit:

unknown

Filed:

herewith

Examiner:

unknown

For:

Reissue of U.S. Patent No. 5,732,711

Issued March 31, 1998

on U.S. Application Serial No. 703,794

Filed August 27, 1996

DECLARATION BY INVENTORS

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

We, Joseph F. Fitzpatrick, Anthony C. Romano, John H. Richards, and Ronald S. Kolarovic declare that we are citizens of the United States of America; that we verily believe ourselves to be the original and first inventors of the invention described and claimed in U.S. Letters Patent No. 5,732,711 (hereinafter '711 PATENT) and in the foregoing specification and for which invention we solicit a reissue patent; that we do not know and do not believe that said invention was ever known or used in the United States of America before our invention thereof; and that we verily believe the '711 PATENT to be wholly or partly inoperative or invalid by reason of our claiming less than we had a right to claim in the '711 PATENT.

We request that we be permitted to amend the '711 PATENT and be granted a reissue patent; that errors rendering the '711 PATENT wholly or partly inoperative or invalid caused the claims of such patent to be of more narrow scope than necessary to distinguish over the prior art; and that such errors arose without any deceptive intent.

Specifically, we at least claimed less than we had a right to claim in the '711 PATENT by included in said patent claim 1 a specific type of temperature sensor.

We have reviewed and understand the contents of the specification as amended herein, including amended original patent claims 1-8, as well as new claims 9-34.

We acknowledge our duty to disclose information of which we are aware which is material to patentability as defined in Title 37, Code of Federal Regulations §1.56; and we

further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the application for reissue or any patent issuing thereon.

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